

Dated: December 7, 1995.
Clifton R. Gaus, Sc.D.,
Administrator.
[FR Doc. 95-30478 Filed 12-13-95; 8:45 am]
BILLING CODE 4160-90-M

Food and Drug Administration

[Docket No. 95G-0389]

Aplin & Barrett Ltd.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Aplin & Barrett Ltd., has filed a petition (GRASP 5G0417) proposing to affirm that nisin preparation is generally recognized as safe (GRAS) as an antimicrobial agent in sauces and nonstandardized salad dressings.

DATES: Written comments by February 27, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3072.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Aplin & Barrett Ltd., c/o 700 13th St. NW., suite 1200, Washington, DC 20005, has filed a petition (GRASP 5G0417) proposing that nisin preparation be affirmed as GRAS for use as an antimicrobial agent in sauces and nonstandardized salad dressings.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and

this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Interested persons may, on or before February 27, 1996, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 21, 1995.

Alan M. Rulis,
Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.
[FR Doc. 95-30500 Filed 12-13-95; 8:45 am]
BILLING CODE 4160-01-F

Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection

techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (Formerly: Remittance Advice Report) and Prior Quarter Adjustment Statement; *Form No.:* HCFA-304, HCFA-304a; *Use:* The Omnibus Budget Reconciliation Act of 1990 requires drug labelers to enter into and have in effect a rebate agreement with HCFA for States to receive funding for drugs dispensed to Medicaid recipients.

The regulation at 42 CFR 447.534 requires labelers to report specific drug rebate data to States when payment is made; *Affected Public:* Business or other for profit; *Number of Respondents:* 520; *Total Annual Responses:* 2,080; *Total Annual Hours Requested:* 170,560. To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collection should be sent within 60 days of this notice direct to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Linda Mansfield, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 7, 1995.

Kathleen B. Larson,
Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95-30475 Filed 12-13-95; 8:45 am]
BILLING CODE 4120-03-P

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any

of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Maximizing the Effectiveness of Home Health Care: The Influence of Service Volume and Integration With Other Care Settings on Patient Outcomes; *Form No.:* HCFA-R-189; *Use:* This study will examine (1) the relationship of home health care service volume and patient outcomes, and (2) the relationship of the physician role and integration of other services and patient outcomes; *Frequency:* Other (periodically); *Affected Public:* Not-for-profit institutions, business or other for profit, and individuals or households; *Number of Respondents:* 6,300; *Total Annual Hours:* 3,573.

2. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services, Outpatient Physical Therapy Speech Pathology Survey Report; *Form Nos.:* HCFA-1856, HCFA-1893; *Use:* The Medicare Program requires outpatient physical therapy providers to meet certain health and safety requirements. The request for certification form is used by State agency surveyors to determine if minimum Medicare eligibility requirements are met. The survey report form records the result of the onsite survey; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 1,700; *Total Annual Hours:* 446.25.

3. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Request for Certification as Supplier of Portable X-ray Services Under the Medicare/Medicaid Programs, and Portable X-ray Survey Report; *Form Nos.:* HCFA-1880, HCFA-1882; *Use:* The Medicare program requires portable x-ray suppliers to be surveyed for health and safety standards. The HCFA-1882 is the survey form that records survey results. The HCFA-1880 is used by the surveyor

to determine if a portable x-ray applicant meets the eligibility requirements; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 520; *Total Annual Hours:* 137.

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization's Request for Designation; *Form No.:* HCFA-576; *Use:* The information provided on this form serves as a basis for certifying organ procurement organizations (OPO) for participation in the Medicare and Medicaid programs and will indicate whether the OPO is meeting the specified performance standards for reimbursement of service; *Frequency:* Biennially; *Affected Public:* Business or other for profit, not-for-profit institutions; *Number of Respondents:* 80; *Total Annual Hours:* 160.

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Physical Therapist in Independent Practice Request for Certification in the Medicare Program; *Form No.:* HCFA-262; *Use:* The HCFA-262 is used by the surveyors to determine if a physical therapist in independent practice requesting Medicare approval meets the eligibility requirements; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 7,322; *Total Annual Hours:* 1,098.

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Request for Approval as a Hospital Provider of Extended Care Services (Swing-Bed) in the Medicare and Medicaid Programs; *Form No.:* HCFA-605; *Use:* The HCFA-605 is used for facility identification and screening. It will be completed by a hospital that is requesting approval and will initiate the process of determining the hospital's eligibility and for which bed count category the hospital wishes to request approval; *Frequency:* Other (one-time usage for initial application); *Affected Public:* Business or other for profit, not-for-profit institutions, Federal Government; *Number of Respondents:* 1,500; *Total Annual Hours:* 375.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to

the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: John Burke, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 7, 1995.

Kathleen B. Larson,
Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95-30474 Filed 12-13-95; 8:45 am]

BILLING CODE 4120-03-P

Health Resources and Services Administration

Rural Health Services Outreach Grant Program

AGENCY: Health Resources and Services Administration, PHS.

ACTION: Notice of availability of funds.

SUMMARY: The Office of Rural Health Policy, Health Resources and Services Administration (HRSA), announces that applications are being accepted for Rural Health Services Outreach Demonstration Grants to expand or enhance the availability of essential health services in rural areas. Grants for these projects are authorized under Section 301 of the Public Health Service Act.

This program announcement for the above stated program is subject to the appropriation of funds for this activity. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, awards can be made in a timely fashion consistent with the needs of the program. At this time, given a continuing resolution and the absence of FY 1996 appropriations for this program, the amount of funds available cannot be estimated.

NATIONAL HEALTH OBJECTIVES FOR THE YEAR 2000: The Health Resources & Services Administration (HRSA) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a Public Health Service (PHS) national activity for setting priority areas. The Rural Health Services Outreach program is related to the priority areas for health promotion, health protection and preventive services. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-C) or Healthy People 2000 (Summary Report: Stock No. 017-001-